Haley Guiliano

6/28/2024 | In the Media News, Thought Leaders

A closer look at the latest PTAB estoppel developments

Introduction

More than a decade ago, the America Invents Act (AIA) changed US patent law, including establishing post-grant proceedings, post-grant review (PGR) and *inter partes* review (IPR), allowing third parties to challenge the validity of patents before the Patent Trial and Appeal Board (PTAB). PGRs, available for patents with a priority date of 16 March 2013 or later, must be filed within nine months of issuance and may assert any ground of invalidity. IPRs, by contrast, can be filed nine months or more after issuance and are limited to prior-art invalidity grounds. In both cases, the prior art can only be patents or printed publications.

Congress established PTAB proceedings to provide a 'quick and cost effective [sic] alternative to litigation' (HR Rep No. 112-98, Part 1, at 45 (2011)). Accordingly, they included estoppel provisions that affect the rights of third parties challenging the validity of a patent both before the PTAB and in litigation.

Specifically, 35 USC 315(e)(2) provides that:

> [t]he petitioner in an [IPR] of a claim in a patent . . . that results in a final written decision . . . or the real party in interest or privy of the petitioner, may not assert . . . in a civil action . . . that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that [IPR].

35 USC 325(e)(2) has identical estoppel provisions for PGRs.

In the biotechnology and pharmaceutical industries, billion-dollar products can be protected by just one or a handful of US patents. Accordingly, life science patent owners should aggressively assert these estoppel provisions after prevailing in a post-grant proceeding in abbreviated new drug application and biosimilar infringement litigation. By contrast, patent challengers should carefully consider the estoppel risks as they develop their overall litigation strategy, including the filing of any IPRs or PGRs.

US PTAB estoppel cases

Various Federal Circuit, district court and PTAB decisions have shaped the contours of these estoppel provisions. While the cases were decided in the context of IPR estoppel, they should apply equally to PGR estoppel because the statutes are identically worded, although the courts may develop different tests for whether non-prior-art invalidity grounds (eg, lack of utility, written description or enablement) that are only available in PGRs could have reasonably been raised. Additionally, while these cases relate to technology patents, they provide useful lessons for life sciences patent practitioners.

During the inter partes review

In *Apple, Inc v California Institute of Technology*, the Supreme Court denied certiorari leaving in place a Federal Circuit decision that Apple was estopped to raise in litigation prior-art obviousness combinations it 'reasonably could have raised' in concurrent PTAB proceedings.

In *Caltech*, the university sued Apple and Broadcom (collectively Apple) for patent infringement. Concurrently with the litigation, Apple filed multiple IPR petitions challenging the validity of Caltech's patents. The PTAB instituted the IPRs and issued final written decisions holding that Apple had not shown that the patents were unpatentable.

Apple then raised new obviousness defences before the district court. It was undisputed that Apple was actually aware of the art that formed the bases of the new defences when filing the IPR petitions but chose not to include the specific combinations, subsequently relied on in the litigation, in those petitions. The district court granted summary judgement of no invalidity holding that Apple was estopped to raise the obviousness defences on the basis of the IPR decisions.

Before the Federal Circuit, Apple argued that estoppel only applied to invalidity grounds that were 'raised or reasonably could have raised during' the IPR. In support, Apple pointed to *Shaw Industries Group, Inc v Automated Creel Systems, Inc*, which held that an IPR 'does not begin until it is instituted'. In *Shaw*, the Federal Circuit opined that a party was not estopped in litigation from raising invalidity grounds on which the PTAB declined to institute an IPR. Apple then went one step further, arguing that because new grounds cannot be added after institution, only the grounds on which the IPR was instituted could reasonably have been raised during the IPR and be the basis of estoppel.

The Federal Circuit disagreed, distinguishing *Shaw* as being decided when the PTAB often instituted IPRs on fewer than all of the grounds raised. Post-*Shaw*, however, the Supreme Court held in *SAS Institute, Inc v Iancu* that the AIA does not authorise institutions on fewer than all of the petitioned grounds. The petition, not the institution decision, therefore, defined the scope of the IPR. As a result, the Federal Circuit in *Caltech* held that 'any ground that could have been raised in a petition is a ground that could have been reasonably raised 'during inter partes review'. Because Apple was aware of the new defences before filing its IPR petitions and chose not to raise them, the Federal Circuit affirmed the district court's estoppel decision.

Estoppel standard and burden

The Federal Circuit has also clarified whether patentee or petitioner carries the burden of establishing estoppel in litigation and the standard that should be used to determine whether prior art could reasonably have been raised in the IPR.

In *Ironburg Inventions Ltd v Valve Corp*, the Federal Circuit partially vacated a district court decision that Valve was estopped to raise invalidity grounds included in the IPR petition but not in the final written decision as a result of a pre-*SAS* partial institution (ie, non-instituted grounds, as well as new invalidity grounds not included in the petition).

Regarding the non-instituted grounds, the Federal Circuit affirmed the district court's estoppel holding. Valve admitted that in view of *SAS,* it could have asked the PTAB to reconsider the partial institution and the other invalidity grounds raised in the petition. Valve did not do so. The Federal Circuit, thus, held that Valve's choice resulted in estoppel with respect to the non-instituted grounds.

In the context of the new grounds, the Federal Circuit first addressed what grounds 'reasonably could have been raised' during the IPR and adopted a skilled searcher standard: a party reasonably could have raised any ground that 'a skilled searcher conducting a diligent search reasonably could have been expected to discover'. Under this standard, the party would not be estopped to assert an invalidity ground that could only be discovered, for example, by a scorched-earth search. While the skilled searcher standard would likely apply to prior-art-based invalidity

grounds in PGRs, it may not apply to non-prior-art-based invalidity grounds available in PGRs (eg, utility, written description and enablement). Accordingly, courts will likely need to establish standards for determining when such grounds reasonably could have been raised in a PGR – perhaps 'a skilled IP attorney' standard.

Next, the Federal Circuit held that the patent owner bears the burden of proving, by a preponderance of the evidence, that a skilled searcher, exercising reasonable diligence, would have identified the new invalidity ground (ie, consistent with the general practice that a party asserting an affirmative defence bears the burden of proving it). That said, a petitioner would be well advised to document the reasonableness of its search and investigation of all grounds of potential invalidity.

On this allocation of the burden, the Federal Circuit vacated the estoppel as to the new grounds of invalidity:

> [b]ecause the district court improperly placed the burden of proof on Valve, to show that it could not 'reasonably . . . have raised' the ['new' grounds] in its petition, when instead the burden of proof rests with [the patentee] to prove that these were grounds Valve 'reasonably could have raised' during the IPR.

Indeed, in *EIS, Inc. v IntiHealth Ger GmbH*, the petitioner was able to avoid PTAB estoppel in a litigation by providing the court with two prior-art searches performed by skilled search firms: one performed prior to filing the IPR petition and the other before serving invalidity contentions in the litigation. Neither contained the art at issue (Yang). While the patent owner also provided two searches, which purportedly identified Yang, the court held that those searches were 'plagued by hindsight bias' because the searchers were provided a copy of Yang before conducting their searches. Indeed, the patent owner's search strings included terms present in Yang but missing from the challenged patents. When those terms were excluded from the search strings, Yang was not identified. Accordingly, patent owners must take care to avoid such hindsight bias when attempting to meet their burden under the skilled searcher standard.

Unavailable prior art

IPR invalidity grounds (and any prior-art-based PGR invalidity grounds) must be based on patents or printed publications. Because PTAB invalidity grounds cannot be based on prior sales or use, patent challengers often contend that they are not estopped to raise such invalidity defences in litigation because they could not have been reasonably raised during the PTAB proceeding. District courts applying *Ironburg's* skilled searcher test have split in addressing this issue, especially when a printed publication (eg, a user manual) describing the prior-art product or use exists.

On one hand, in *Carolyn W Hafeman v LG Electronics Inc*, the district court held that LG was estopped form relying on two alleged prior-art products (ie, the products themselves, not publications describing them). Even though the products could not have been included as invalidity grounds in the IPR, the court held that 'estoppel still applies when the allegedly new references have 'materially identical' disclosures as the IPR art'. The IPRs relied on prior-art patents and based on LG's admissions, the court found that the products practise those patents because there was 'no substantial difference' between the products and the patents and LG was estopped.

By contrast, in *Singular Computing LLC v Google LLC*, the court held that Google was not estopped to raise invalidity defences based on prior-art CPU systems after losing on its 'patents and publications' invalidity grounds before the PTAB. The court noted that the AIA:

> says nothing about estopping invalidity claims that are 'cumulative' or 'duplicative' of those raised in an IPR proceeding. Nor does it specify that evidence outside of patents or publications is permissible only

> when that evidence provides the sole support for a claim limitation.

Accordingly, the court held that:

> an accused infringer who receives a final written decision in an IPR proceeding may challenge the validity of a patent in … district court, but only to the extent that the challenge is based on prior-art evidence that it could not have presented in a petition for IPR.

Interestingly, the court also held that Google could only raise invalidity grounds based solely on prior-art evidence that it could not have presented in the IPR (the CPU systems) but was estopped from arguing obviousness based on a combination of the CPU systems with a prior-art patent or printed publication (ie, that could have been raised in an invalidity ground in the IPR), even though such a combination would not have been permitted in the IPR.

In *Prolitec Inc. v Scentair Techs., LLC*, Federal Circuit Judge Bryson (sitting by designation in D Del) held that 'IPR estoppel does not apply to device art, even when that device art is cumulative of patents and printed publications that were or could have been asserted in a prior IPR'. Judge Bryson focused on the Federal Circuit's use of 'ground' 'to mean a legal argument based on a specific combination of references' and, therefore, 'as the specific pieces of prior art that are the bases on which a petitioner challenges a claim'. Because the prior-art product could not have been raised in the earlier IPR, the estoppel provisions of 35 USC 315(e)(2) did not apply. The court in *EIS, Inc. v IntiHealth Ger GmbH* similarly held that 'IPR estoppel does not apply to products covered by the actual prior-art reference underlying the IPR where the actual prior-art reference discloses the same claim limitations as the product'.

Estoppel in other patent office proceedings

IPRs also have estoppel effects on invalidity challenges in other patent office proceedings. Similar to the estoppel in litigation, defendants who fail in their patent challenge in an IPR are estopped in subsequent invalidity challenges in the Patent Office from pursuing grounds, which they raised or could have raised in the earlier IPR. Indeed, the United States Patent and Trademark Office (USPTO) recently held that Salesforce, which, as a real-party-in-interest in prior IPRs, had unsuccessfully challenged two AIT patents, was estopped from challenging the patents in ex parte re-examinations (see Ex parte Reexamination 90/019,069, Decision on Petitions (USPTO, 25 May 2023) and Ex parte Reexamination 90/019,070, Decision on Petitions (USPTO, 25 May 2023)). In the IPRs, the PTAB issued final written decisions finding that several claims were unpatentable. The Federal Circuit vacated those decisions, and the PTAB terminated the IPRs on remand.

In the re-examinations, AIT argued that Salesforce was a real-party-in-interest in the earlier IPRs, which had resulted in final written decisions and, therefore, was estopped to request ex partere-examination on invalidity grounds that were raised or could have been raised in the IPRs. Salesforce argued, on the other hand, that estoppel should not apply given the Federal Circuit's vacatur. Citing *Intuitive Surgical, Inc v Ethicon LLC*, the USPTO held that the vacatur did not negate the statutory estoppel effect of the final written decisions. In particular, the USPTO noted that in *Intuitive Surgical,* the Federal Circuit held that the estoppel occurs upon the issuance of the final written decisions. Vacatur does not change that fact. The re-examination requests also relied on additional art as compared to the IPRs. As to that art, the USPTO applied the skilled searcher test and determined that the art reasonably could have been raised in the IPRs. The USPTO, therefore, terminated the re-examination proceedings.

Common law issue preclusion does not expand inter partes review or post-grant review estoppel

The court in the Central District of California held that common law issue preclusion (an earlier final judgment binds the parties as to issues actually litigated in the prior action) cannot be used to bar a challenger's invalidity grounds

that could not have been reasonably raised in a related IPR. In *DMF, Inc v AMP Plus, Inc*, DMF moved to estop AMP from raising invalidity grounds that were raised or could have been raised in an earlier IPR, which resulted in a final written decision finding that most of the challenged claims were not unpatentable. The district court granted the motion with respect to invalidity grounds that were based on prior-art patents and printed publications but denied the motion with respect to invalidity grounds based on a prior-art product, which could not have been raised in the IPR and which it found to be substantively and germanely different from a catalogue relied on in the IPR because the catalogue did not disclose every feature of the product.

DMF then argued that common law issue preclusion barred AMP's product-based invalidity grounds. The district court denied the motion, finding that 35 USC 315(e)(2) 'embodies an evident statutory purpose to apply the specified framework in lieu of common law issue preclusion'. Accordingly, common law issue preclusion was not appropriate '[b]ecause Congress enacted a specific framework with respect to the issue preclusive effect of IPR proceedings'.

Conclusion

As courts continue to shape and refine the metes and bounds of PTAB estoppel on subsequent invalidity challenges in the district courts and the Patent Office, patent challengers should carefully consider their strategies for invalidating biotechnology and pharmaceutical patents. The lower burden of proof in a PTAB proceeding (preponderance of the evidence) as compared to a district court infringement litigation (clear and convincing evidence) and the availability of technically trained administrative patent judges still makes the PTAB an attractive venue for challenging patents. Petitioners in the generic and biosimilar industries, however, should be sure to present all of their arguments and not to hold any back in reserve, because they likely will be estopped to raise them in subsequent proceedings directed to patent claims upheld in the IPR or PGR. Further, until the Federal Circuit weighs in on how estoppel applies to prior-art products or non-prior-art invalidity grounds in PGRs, challengers should have these uncertainties in mind as they develop their strategies in the PTAB and subsequent litigation. Many generic or biosimilar producers may file 'clear the path' PTAB proceedings ahead of their FDA submissions. If such clear the path PTAB challenges are unsuccessful, the generic or biosimilar producer may have to either wait for the patent to expire before commercially launching their product or design around the unsuccessfully challenged patent. Therefore, these potential clear the path challenges should be carefully evaluated in view of any subsequent product development or litigation strategies.

This article first appeared *IAM Life Sciences: Key issues for senior life sciences executives 2024,* a supplement to *IAM,* published by Law Business Research – IP Division. To view the guide in full, please go to www.iam-media.com .'

Authors

Partner

Brian Gummow

Partner

Karen Mangasarian

Partner

James F. Haley, Jr.